

AMENDMENTS TO THE CLAIMS

Please amend claims 3, 5, 6, 8, 9, 11, 13 and 14, and cancel claims 7 and 15 without prejudice, such that the status of the claims is as follows:

1. (Original) A composition comprising a niosome, wherein the niosome retaining within its structure:

(1) a cyclodextrin inclusion complex formed by a cyclodextrin compound and a steroidal active agent; and

(2) a vesicle formed by a nonionic surfactant;

wherein said niosome can facilitate the transdermal delivery of said steroidal active agent.

2. (Original) The composition of claim 1, wherein said steroidal active agent is selected from the group consisting of progestogens, corticosteroids, estrogens, and androgens.

3. (Currently Amended) The composition of claim 1, wherein said cyclodextrin compound is selected from the group consisting of α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, methyl-cyclodextrin, propyl-cyclodextrin, isopropyl-cyclodextrin, hydroxymethyl-cyclodextrin, hydroxyethyl-cyclodextrin, hydroxypropyl-cyclodextrin, and sulfoalkyl-cyclodextrin.

4. (Original) The composition of claim 3, wherein said cyclodextrin compound is β -cyclodextrin.

5. (Currently amended) The composition of claim 1, wherein said cyclodextrin

inclusion complex is comprised of a cyclodextrin compound and a steroidal active agent in a molar ratio of about ~~1.0 to 10.0~~ 10.0 to 1.0.

6. (Currently amended) The composition of claim 1, wherein said nonionic surfactant is selected from the group consisting of ~~alcohols~~, polyalkylene oxide derivatives such as polyethylene oxide, copolymers of ethylene and propylene oxide, condensates of ethylene and propylene oxide with fatty alcohols, polyethoxylated fatty amides having from 2 to 30 mol of ethylene oxide; alkyl polyglycosides ~~[[,]]~~ such as C₆-C₂₄ alkyl polyglycosides; derivatives of N-alkyl glucamine including N-(C₆-C₂₄)alkyl glucamine; fatty acid esters of sucrose; fatty acid esters of polyethylene glycol; (C₆-C₂₄)alkyl polyglycosides; derivatives of N-(C₆-C₂₄)alkyl glucamine; alkylamine oxides such as C₆-C₂₄ alkylamine oxides and N-(C₁₀-C₁₄)acylaminopropylmorpholine oxides; sorbitol monostearate type surfactant such as Span 60 and polyoxyalkylene sorbitan monostearate type surfactant such as Tween 20, Tween 40, Tween 60 and Tween 80.

7. (Canceled).

8. (Currently amended) The composition of claim 1, wherein said niosome is comprised of a nonionic surfactant vesicle and a cyclodextrin in a molar ratio of about 1.0 to 25.0 ~~25.0 to 1.0~~.

9. (Currently amended) A method of producing a composition comprising a niosome, wherein the niosome retaining within its structure:

(1) a cyclodextrin inclusion complex formed by a cyclodextrin compound and a steroidal active agent; and

(2) a vesicle formed by a nonionic surfactant;

wherein said niosome can facilitate the transdermal and/or transmucosal delivery of said steroidal active agent,

the method comprising the steps of:

(a) forming a cyclodextrin inclusion complex of a steroidal active agent;

(b) forming a vesicle solution of a nonionic surfactant;

(c) mixing the vesicle solution of step (b) with the cyclodextrin inclusion complex of step (a) in a molar ratio of about ~~1.0 to 25.0~~ 25.0 to 1.0; and

(d) drying the resulted mixture of step (c).

10. (Original) The method of claim 9, wherein said steroidal active agent is selected from the group consisting of progestogens, corticosteroids, estrogens, and androgens.

11. (Currently amended) The method of claim 9, wherein said cyclodextrin compound is selected from the group consisting of α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, methyl-cyclodextrin, propyl-cyclodextrin, isopropyl-cyclodextrin, hydroxymethyl-cyclodextrin, hydroxyethyl-cyclodextrin, hydroxypropyl-cyclodextrin, and sulfoalkyl-cyclodextrin.

12. (Original) The method of claim 11, wherein said cyclodextrin compound is β -cyclodextrin.

13. (Currently amended) The ~~composition~~ method of claim 9, wherein said cyclodextrin inclusion complex is comprised of a cyclodextrin compound and a steroidal active agent in a molar ratio of about ~~1.0 to 10.0~~ 10.0 to 1.0.

14. (Currently amended) The method of claim 9, wherein said nonionic surfactant is selected from the group consisting of ~~alcohols~~, polyalkylene oxide derivatives such as polyethylene oxide, copolymers of ethylene and propylene oxide, condensates of ethylene and propylene oxide with fatty alcohols, polyethoxylated fatty amides having from 2 to 30 mol of ethylene oxide; alkyl polyglycosides ~~[[,]]~~ such as C₆-C₂₄ alkyl polyglycosides; derivatives of N-alkyl glucamine such as N-(C₆-C₂₄)alkyl glucamine; fatty acid esters of sucrose; fatty acid esters of polyethylene glycol; (C₆-C₂₄)alkyl polyglycosides; derivatives of N-(C₆-C₂₄)alkyl glucamine; alkylamine oxides such as C₆-C₂₄ alkylamine oxides or N-(C₁₀-C₁₄)acylaminopropylemorpholine oxides; sorbitol monostearate type surfactant such as Span 60 and polyoxyalkylene sorbitan monostearate type surfactant such as Tween 20, Tween 40, Tween 60 and Tween 80.

15. (Canceled).

16. (Original) The method of claim 9, wherein said mixing of step (a) is a physical mixing process or a freeze-drying process.

17. (Original) The method of claim 16, wherein the physical mixing process characterized in grinding a mixture of a cyclodextrin compound and a steroidal active agent in a grinder until the mixture is homogenous.

18. (Original) The method of claim 16, wherein the freeze-drying process characterized in having the steps of:

- (a) mixing an aqueous solution of a cyclodextrin compound and an alcoholic solution of a steroidal active agent;
- (b) evaporating the solvent of said solution mixture of step (a); and
- (c) freeze-drying the resulted mixture of step (b).

19. (Original) A method of facilitating transdermal delivery of a steroidal active agent, comprising administering to a human or an animal the composition of claim 1.